

MAR 17 2004

K44538

2.6

510(k) Summary

Submitter: American Medical Systems
10700 Bren Road West
Minnetonka, MN 55343
Phone: 952-933-4666
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Contact Person: Denise Thompson

Date Summary Prepared: February 27, 2004

Device Common Name: Urethral Sling, Surgical Mesh

Device Trade Name: BioArc TO™ Subfascial Hammock

Device Classification Name: Surgical Mesh, polymeric

Predicate Device: BioArc SP™ Sling Kit, K030123
MONARC™ subfascial hammock, K023516

Device Description:

The BioArc TO Subfascial Hammock is a suburethral sling procedure that uses a transobturator surgical approach to treat stress urinary incontinence. It is a sterile, single use procedure kit consisting of two stainless steel helical shaped needle passers and a mesh sling assembly to which graft material is attached.

Indications for Use:

BioArc TO Subfascial Hammock is intended for the placement of a suburethral graft for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

Comparison to Predicate Device:

The BioArc TO brings two currently marketed AMS technologies, the BioArc SP Sling Kit and the Monarc subfascial hammock, together into one procedure.

The Indications for Use, fundamental scientific technology, surgical approach, sling placement, and materials are all the same as one of the two predicates.

Supporting Information:

The risk analysis and the verification / validation activities reported in this Special 510(k) application substantiate equivalence to the predicate devices and did not raise any new questions of safety or efficacy.

Conclusion:

The BioArc TO Subfascial Hammock is substantially equivalent to its predicates with respect to intended use, technological characteristics, and performance.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 17 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Denise Thompson
Regulatory Specialist
American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, Minnesota 55343

Re: K040538

Trade/Device Name: AMS BioArc™ TO Subfascial Hammock
AMS BioArc™ SP Sling Kit

Regulation Number: 21 CFR 878.3300

Regulation Name: Surgical mesh

Regulatory Class: II

Product Code: FTL

Dated: March 1, 2004

Received: March 2, 2004

Dear Ms. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

1.4

INDICATIONS FOR USE STATEMENT

K040538

510(k) Number (if known):

Device Name: AMS BioArc™ SP Sling Kit

Indications For Use:

The BioArc SP Sling Kit is intended for the placement of a pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and / or intrinsic sphincter deficiency.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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